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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,855	02/20/2004	Werner Doetsch	038715.53046US	1653
23911 7590 07/24/2007 CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			EXAMINER SAYALA, CHHAYA D	
			ART UNIT 1761	PAPER NUMBER
			MAIL DATE 07/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/781,855	<b>Applicant(s)</b> DOETSCH ET AL.	
	<b>Examiner</b> C. SAYALA	<b>Art Unit</b> 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/21/2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4 and 8-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4 and 8-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/2007 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 4, 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation "on a molecular level" could not be found in the specification, neither was such a concept. Upon applicant pointing out where this occurs this rejection will be withdrawn. If applicant cannot locate basis for this limitation either, it is required that all references to this be cancelled. This is a new matter rejection. This

rejection is being maintained because the specification does not provide sufficient evidence to persons skilled in the art that the specification as filed contemplated the limitation now claimed. See MPEP 2163. The standard for evaluating new matter in the claims is not whether the subject matter would be obvious to one skilled in the art from the specification as originally filed. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). See MPEP 2163.02.

Applicant's claims recite that "calcium peroxide and magnesium peroxide that are homogeneously dispersed in each other on a molecular level, and the boron is homogeneously distributed within the mixed calcium/magnesium peroxide."

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Prior art is limited to the one disclosure wherein patentees state that the mixing of suspensions/liquids/solutions of reactants and subsequent drying led to them being "homogeneously distributed in each other on a molecular level".

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 4, 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doetsch et al. (US Patent 6193776) in view of GB 1580248 and further in view of GB 1575792.

Doetsch et al. teach homogeneous calcium/magnesium peroxide with an active oxygen content of 10-18% by wt. The composition includes a peroxygen stabilizing amount of a stabilizer. (See claim 11). A process for preparing this homogeneous calcium/magnesium peroxide composition is also taught. See col. 3, lines 15+ which discloses the details of preparation of such a homogeneous composition of calcium/magnesium peroxide including stabilizer: an aqueous suspension of calcium and magnesium hydroxides are reacted together with aqueous hydrogen peroxide. The

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water is evaporated and the product is dried. Small amounts of stabilizer are added before, simultaneously or after the reaction with hydrogen peroxide. This results in the product having calcium peroxide and magnesium peroxide *homogeneously dispersed in each other on a molecular level*. See claim 4. The patent does not teach a boron content or boron compounds.

The GB '248 teaches a calcium peroxide amount of up to 50% and 0 to 5% of boric acid in a solution which are fed into a granulator and then dried. A granulator inherently would mix the ingredients to homogeneity. The patent teaches treating sugar beet seeds with calcium peroxide, 0.01 and 90.0% by weight, for improving the quality of the beet. The boron additive is added in an amount 0 to 10%, preferably 0 to 5% by wt. (see page 2, lines 10-25; page 1, lines 25-30). At page 2, lines 25+, the patent teaches how to coat the beet seeds with calcium peroxide and the compounds "used for improving the quality of the beet such as for example boron derivatives, in particular boric acid, borax and sodium perborate". At page 2, line 26, the patent states "The coating operations can be carried out in any manner known in itself in various types of apparatus known in themselves, including for instance, granulators. These are fed with seed, calcium peroxide and possibly fillers, **water** and other additives. The resulting grains are then dried." (emphasis added).

Thus '248 also teaches essentially a similar method, which is taking calcium peroxide and the boron compound *in water*, reacting it in the presence of the seed, and then drying it. Such a process, which is similar to the Doetsch et al. teaching, would inherently produce a homogeneously distributed boron within the calcium/magnesium

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peroxide, and one of ordinary skill in the art would have known that at the time the invention was made, based on the teachings of Doetsch et al.

GB '792 teaches that peroxygenated compounds have a high stability with compounds such as sodium perborate. Line 53 at page 1 states "In order to improve the stability of the peroxygenated compounds it has also been suggested that the peroxygenated compounds be mixed in the solid phase with metaboric acid". In addition, page 1, in citing prior art, states:

"it has been suggested in the French Patent 750125, filed on 30.11.1932 in the name of Oesterreichische Chemische Werke Gesellschaft that various types of stabilising agents be introduced during the manufacture of the said per-oxygenated compounds by reacting salts or corresponding solid oxides with an aqueous solution of hydrogen peroxide, these stabilizing agents being capable of dissolution in the aqueous solution of hydrogen peroxide and/or mixed in the solid phase with the original oxides or salts."

Such a teaching provides motivation to substitute the stabilizers of Doetsch et al. with stabilizing compounds shown by '792 and to incorporate such in the primary patent as functionally achieving the stabilization of the homogeneously distributed peroxygen compound on a molecular level when taken with the '248 teachings.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the peroxygenated compounds of the primary references with boric acid, which adds stability to the peroxygenated compounds, as taught by the method of Doetsch et al., i.e. by adding the boron compound and the peroxygen compound with water so as to give a suspension and/or solution and reacting them together and drying them out. This is the same method used by '248 to coat beet seeds. See page 2, lines 25-30 in '248. To substitute the method of Doetsch

et al. with boron compounds which are shown to stabilize peroxygenated compounds, when Doetsch et al. already uses stabilizers, would have been prima facie obvious. Further, since Doetsch et al. teach the method of obtaining products that are homogeneously distributed on a molecular level, even with stabilizers, then to follow the same method with boron compounds would have been obvious to one of ordinary skill in the art at the time the invention was made with the reasonable expectation that the compounds are homogeneously distributed on a molecular level. GB '792 provides the motivation to make the substitution of boron compounds for the Doetsch et al. stabilizers, since the patent teaches that boron compounds are stabilizers for peroxides *and* the GB '248 patent teaches coating beet seeds with peroxygen and boron compounds combined in a water solution and drying them, steps also followed by Doetsch et al. Note '792 at page 3, line 108 and page 4, line 56, which include the concept of homogenization in its incorporation of peroxide and boron compounds.

### ***Response to Arguments***

Applicant's arguments filed 6/21/2007 have been fully considered but they are not persuasive.

With respect to the 35 USC 112, second paragraph rejection, applicant's explanation of "on a molecular level" as being "individual molecules of boron dispersed among individual molecules of calcium and magnesium peroxide, as opposed to clumps of boron compound being dispersed among the particles of calcium and magnesium peroxide" does not cause withdrawal of the rejection because, "clumps of boron



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compound” are not devoid of molecules or atoms. An “atom” is defined as “The smallest part of an element that remains unchanged during chemical reaction and is thus chemically indestructible and indivisible”. A molecule is defined as “the chemical combination of two or more like or unlike atoms” and “The smallest quantity of matter that can exist in the free-state and retain all its properties” (Grant and Hackhs’ Chemical Dictionary, Fifth edition). Therefore, whether they may be in clumps or particles, dispersed or distributed, the compounds are on a “molecular level” because, they are all made up of molecules.

With respect to the 35 USC 112, first paragraph rejection, applicant’s argument is that although “on a molecular level” may not be found in the specification but, it is inherent, when the process or reaction occurs and a skilled artisan would understand that reacting an aqueous solution/suspension of an alkaline earth peroxide and hydrogen peroxide with a boron compound containing solution would result in boron being distributed in the peroxide on a molecular level. This explanation, in the absence of enough support in the specification, of any molecular level studies or substantiating evidence is untenable. When compounds in solution undergo a reaction, they would form intermediate and/or final compounds, which would obviously be different from the reactants by virtue of the fact that they have undergone a reaction. See claim 1, which includes a step of “reacting”. With no description, no support and no definition in the specification, what one of ordinary skill in the art would expect is that mixing solutions of the peroxide compounds with a solution of boron compounds would produce a

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homogeneous solution of reactants, which after reaction would yield a solution of the final product, which when evaporated, yields the boron doped alkaline earth peroxide. Since applicant's limitations now in the claims, are specifically added and argued to establish patentability, and differs from what would be the expected reaction path, the rejection will be maintained.

With respect to the 35 USC 103 rejection over the applied references, applicant argues that none of the cited references discloses or suggests a homogeneous boron doped alkaline earth peroxide, or boron homogenously distributed within the alkaline earth peroxide on a molecular level. In response:

1. Doetsch et al. teach preparation of calcium peroxide/magnesium peroxide mixed together homogenously at a molecular level with a peroxygen stabilizer.
2. GB '792 shows that stabilizing such peroxygenated compounds with boron compounds is advantageous.
3. GB '248 shows mixing calcium peroxide with boron compounds as stabilizers and with beet seeds, providing evidence that calcium peroxide/boron compound mixtures have been used to treat beet seeds.
4. Applicant has stated on the record that when aqueous suspensions or solutions are mixed together and evaporated, then inherently, as one skilled in the art would know, the boron compounds would necessarily be distributed in the peroxide "on a molecular level".

At page 7, applicant states that substitution of the stabilizer of Doetsch et al. with boron compounds of GB '792 is incorrect because, '792 "coats" to stabilize the peroxygenated compound, and is stabilized "by distributing boron homogeneously within the material". In response, this is not the only reference that teaches that boron compounds stabilize peroxygenated compounds, and the prior art discussion on page 1 of the reference clearly shows that mixing salts of peroxygenated compounds with metaboric acid stabilizes them. In addition, this reference is being relied on for its teaching that boron compounds stabilize peroxygenated compounds and that boron compounds act as stabilizers.

Again, Applicant has stated on the record that when aqueous suspensions or solutions are mixed together and evaporated, then inherently, as one skilled in the art would know, the boron compounds would necessarily be distributed in the peroxide "on a molecular level".

With regard to applicant's remarks at page 6, that granulation is a process in which powder particles are made to adhere to form larger multi-particles as pointed out in Summers ("Granulations"), and therefore, would not include homogenization or mixing, Summers actually states (emphasis added):

#### **"INTRODUCTION TO GRANULATION**

Granulation is the process in which primary **powder** particles are made to adhere to form larger, multiparticle entities called granules. Pharmaceutical granules typically have a size range between 0.2 and 4.0 mm, depending on their subsequent use. In the majority of cases this will be in the production of tablets or capsules, when granules will be made as an intermediate product and have a typical size range between 0.2 and 0.5 mm, but larger granules are used as a dosage form in their own right (see Chapter 24).

Granulation normally commences after initial dry mixing of the necessary powdered ingredients so that a uniform distribution of each ingredient through the mix is achieved. After granulation the granules will either be packed (when used as a dosage form), or they may be mixed with other excipients prior to tablet compaction or capsule filling. “

and it is being maintained that mixing in any form results in homogenization “at the molecular level”, since all compounds contain molecules.

At page 7, applicant states that stabilization of peroxygenates involves stabilizing the core or stabilizing with a protective coating, as per Exhibit A, and therefore it would not have been obvious to disperse the boron within the peroxide. In response, this is not the only reference that teaches that boron compounds stabilize peroxygenated compounds, and the prior art discussion on page 1 of the reference clearly shows that mixing salts of peroxygenated compounds with metaboric acid stabilizes them. In

addition, this reference is being relied on for its teaching that boron compounds stabilize peroxygenated compounds and that boron compounds act as stabilizers.

Applicant then states that based on these two methods, it would not have been obvious to the skilled artisan, to earth disperse the boron throughout the alkaline metal peroxide or the homogenous molecular level incorporation of boron within the peroxide. In response, as earlier stated the reference has been relied on only for its teaching that boron stabilizes peroxygen compounds and whether they be in a coating or elsewhere, one of ordinary skill in the art would have expected the boron compound to stabilize the peroxygenated compound. Furthermore, applicant has stated on the record that when aqueous suspensions or solutions are mixed together and evaporated, then inherently, as one skilled in the art would know, the boron compounds would necessarily be distributed in the peroxide "on a molecular level".

The rejection is under 35 USC 103, and has been made over a number of references to be considered together. Therefore, applicant has improperly criticized the references individually where the rejection is based upon the combined teachings of the references. *In re Merck., Inc.*, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986); *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Unobviousness cannot be established by attacking references taken individually when rejection is based on a combination of references. *Ex parte Campbell* 172 USPQ 91 (BPA&I 1971).

### ***Conclusion***

This is a continuation of applicant's earlier Application filed 2/20/2004. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

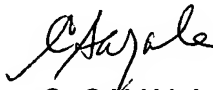
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. SAYALA whose telephone number is 571-272-1405.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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